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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/662,790	09/15/2000	Mark Chandler	215063.02301	2090

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EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/662,790

Applicant(s)

CHANDLER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 19 May 2004 has been entered.

Claims 1-7 are currently pending.

The rejections under 35 USC 102(b) of claims 1-7 over Kettman et al. (Cytometry (1998) Vol. 33, pages 234-243) have been withdrawn in view of Applicant's response.

Priority

Priority to provisional US application 60/153,941 remains denied for the reasons stated in the previous Office Action. The priority date that is granted is the filing date of 15 September 2000.

Applicant further argues that "for reasons set forth on the Responses filed previously in the case, the priority date of September 15, 1999, the filing date of Provisional Application 60/153,941, is the proper priority date for the present application".

This is not persuasive and Applicant is referred to the previous rejection in the Office Action dated 22 January 2004. The question remains that the provisional application fails to fully support the instant claims. The provisional application lacks a full description of the MAP analyte panel as claimed herein. For example, the provisional application does not outline the specifics of the panel, such as containing 75 or more subsets of microspheres, expressing fluorescent signatures, and harboring a reagent.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 remain rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 7, and 8 of U.S. Patent No. 6,524,793 B1 in view of WO 99/19515 (22 April 1999-PTO Form 1449), as stated in the Office Action of 4 August 2003. Applicant states that a Terminal Disclaimer was filed in the response of 22 March 2004, however, no such Disclaimer has been received by the Office. Please kindly re-submit the document.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 recites “harboring at least one reagent”. It is unclear what is meant by “harboring”. Does this mean containing a reagent or something else? Clarification is requested.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by “such as” and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1 and 7 recite the broad recitation “not specifically”, and the claim also recites “selectively” which is the narrower statement of the range/limitation. Clarification is requested.

Also in the present instance, claim 2 recites the broad recitation “or more”, and the claim also recites “100 or 200 or 300” which is the narrower statement of the range/limitation.

Claim 5 recites “natural product”. It is unclear what limitation is intended by “natural product”, as this could include any known natural product. Clarification is requested.

Claim 7 recites “comprising associated buffers”. It is unclear with what the buffers are associated? Clarification is requested.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kettman et al. (Cytometry (1998) Vol. 33, pages 234-243), in view of Ekins et al. (Journal of Pharmaceutical and Biomedical Analysis (1989) Vol. 7, pages 155-168).

Kettman et al. teach a method and system for analysis of multiple analytes in a single

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Sample, as recited in claims 1-7. (see abstract, page 234). “The vehicle for each separate measurement consists of a set of microspheres identifiable by characteristic fluorophores embedded in the particles. The use of robust bench-top flow cytometers for the analysis of the multiple sets of microspheres is facilitated by hardware and software, which acquire the data from cytometer, classify the microspheres according to sets, and collate measurement information for each set of microspheres in real time. This measurement system can analyze up to 64 analytes in a single sample”. Kettman et al. teach a method for the analysis of multiple analytes in a single sample in which the vehicle for each separate measurement consists of a set of microspheres identifiable by their characteristic fluorophores embedded in the particles (abstract, column 1). Kettman et al. describe the design and construction of the FlowMetrix™ microspheres on page 325, column 2. Specifically, the molecules attached to the microsphere surface are called the “target” molecules and consist of two fluorescent dyes (orange and red). The labeled molecules that bind the microsphere are called the “reporter” (green). Furthermore, Ketmann et al. also describe that these panels are useful for analysis of antibodies, antigens, and other soluble molecules, including nucleic acids, drugs, and enzymes (see introduction).

Kettman et al. do not teach 75, 100, 200, 300 or more subsets of microspheres or 75 analytes in an analysis. However, Ekins teaches a multi-analyte immunoassay in which tens or hundreds of substances can be measured simultaneously (abstract), therefore suggesting increasing the analyte and microsphere values in order to increase the capability of medical diagnosis and drug design, for example. It would have been prima facie obvious to one of ordinary skill in the art at the time of invention to have incorporated more than 75 analytes/microspheres into the invention of Kettman et al., as suggested by Ekins. One would be

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motivated to do so by the teachings of Ekins, which state that “fluorescent labels are particularly useful in this context because they readily permit arrays of different antibody “microspots” distributed over a surface, each directed against a different analyte, to be individually examined, thus enabling multiple assays to be simultaneously carried out on the same small sample. The same principals are clearly applicable using other forms of label (page 166, lines 16-21)”. One of ordinary skill in the art would have reasonably expected success in using hundreds of microspheres because Ekins teaches, “it is both conceivable and within the range of present technology that immunoprobes will be developed capable of measuring every hormone (or iso-hormone component), together with other endocrinologically related substance within a single small sample of blood, providing data which, when analyzed with the aid of computer based “expert” pattern recognition systems, will reveal endocrine deficiencies only dimly perceived using current “single analyte” diagnostic procedures (page 167, lines 12-19)”.

No claims are allowed.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO’s Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is

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(866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

July 1, 2004
Lori A. Clow, Ph.D.
Art Unit 1631
Lori A. Clow

MARJORIE MORAN
PATENT EXAMINER

Marjorie A. Moran
7/1/04